Congress of the United States
Washington, DC 20515

March 9, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Secretary Azar:

We write to express our strong opposition to portions of the recently released 2021 Notice of Benefit and Payment Parameters (NBPP) proposed rule.[i] Specifically, we are concerned that this proposed rule would reverse a patient-friendly policy about how health plans treat cost-sharing assistance and make it even harder for patients to afford their medicines. While we value your partnership and interest in addressing high drug pricing, we believe the provisions in the proposed rule would put life-saving medications out of the hands of patients who need them.

Millions of vulnerable Americans across the country rely on cost-sharing assistance to afford the medicines they need. Patients in the private health insurance market have increasingly relied on this assistance due to rising out-of-pocket costs for drugs. Historically, when a patient has used cost-sharing assistance at the pharmacy counter, the amount has counted towards a patient's deductible and maximum out-of-pocket limit. But recently, many health plans started designing benefits to exclude cost-sharing assistance from counting toward patient maximum out-of-pocket limits and deductibles.

As you know, in April 2019, the Department of Health and Human Services (HHS) finalized the 2020 NBPP final rule,[ii] which made important progress on patient affordability by requiring that, in many cases, cost-sharing assistance be counted towards patients' maximum out-of-pocket limits.[iii] The rule also gave employer-sponsored health plans and health insurance issuers flexibility to not count assistance for brand drugs when a generic equivalent is available and medically appropriate. This approach would have ensured that patients could use cost-sharing assistance to afford their needed medications, while preserving plans' ability to control costs.

We are now concerned that the Administration is proposing to reverse this patient-focused policy in the 2021 NBPP. Specifically, we are concerned that the 2021 NBPP proposes to interpret the definition of "cost sharing" in a way that would allow plans to exclude cost-sharing assistance from the out-of-pocket maximum. We believe this does not align with HHS's own definitive regulation on cost sharing,[iv] nor does it align with Congressional intent in defining cost-sharing

and establishing the annual limit on cost sharing. By diluting what counts as cost sharing, HHS would be making it harder for patients to manage high out-of-pocket costs.

Additionally, while the proposed 2021 NBPP cites a 2004 Internal Revenue Service Q&A[v] as justification to diverge from the 2020 NBPP final rule, we do not think this is an insurmountable obstacle. We urge the Department to expeditiously work with the Department of Treasury and stakeholders to come to a solution and note that nothing in the Internal Revenue Code prohibits participants in HSA-eligible HDHPs from having manufacturer cost-sharing assistance apply to their deductibles.

With patient out-of-pocket costs skyrocketing, we oppose any regulatory changes that would hinder patients' ability to afford their medicines. It is our fear that many patients will opt to ration their medicines, or leave their medications at the pharmacy counter altogether, which could lead to more serious health conditions and higher costs. This stands to have a disproportionate impact on individuals from vulnerable populations, people of color, and those with lower incomes and poorer health. We should be doing everything we can to increase affordability options, not limit them.

We urge you to reconsider finalizing the 2021 NBPP's misguided policy on cost-sharing assistance and ensure that provisions pertaining to consumer out-of-pocket costs are consistent with the 2020 NBPP's policy. We believe this would help patients continue to afford their medicines by requiring cost-sharing assistance to count towards patients' out-of-pocket maximum when a medically appropriate generic equivalent is not available.

Sincerely,

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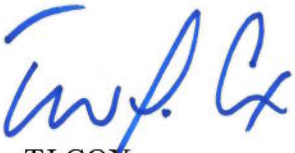

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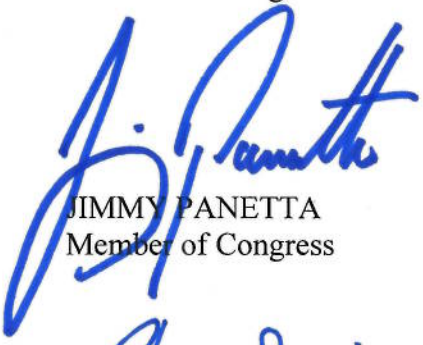

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cc: Secretary Steven T. Mnuchin, Department of Treasury
Secretary Eugene Scalia, Department of Labor

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[i] 85 Fed. Reg. 7088 (Feb. 6, 2020).
[ii] 84 Fed. Reg. 17454 (Apr. 25, 2019).
[iii] *Id.* at 17545.
[iv] 45 CFR § 155.20; see also 45 CFR §§ 156.20, 156.130.
[iv] 42 U.S.C. § 18022(c)(3)
[v] IRS Notice 2004-50, Q&A-9.